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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/517,784

12/13/2004

Gideon Gross

GROSS32

4624

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EXAMINER

DUFFY, BRADLEY

ART UNIT

PAPER NUMBER

1643

MAIL DATE

DELIVERY MODE

04/09/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/517,784	Applicant(s) GROSS ET AL.	
	Examiner BRAD DUFFY	Art Unit 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) _____ is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>see attached notice of non-responsive amendment</u> . |

Notice of Non-Responsive Amendment

1. The amendment filed November 29, 2007, is non-responsive for the following reason:

The amendment filed November 29, 2007, would amend all claims, which were previously drawn to the elected invention, so as to only present claims drawn to a non-elected invention.

The claims, as would be amended, are not readable on the elected invention for the following reasons:

The claims, as would be amended, would be directed to a polynucleotide encoding a polypeptide which comprises, in part, at least one antigenic peptide comprising an MHC class I epitope, wherein said antigenic peptide is *not capable of activating autoreactive cells causing an autoimmune disease*.

In contrast, the originally presented claims, which were examined on the merits, were directed to a polynucleotide encoding a polypeptide which comprises, in part, at least one antigenic peptide comprising an MHC class I epitope, wherein said antigenic peptide is *not related to an autoimmune disease*.

In this case, Applicant has submitted at page 23 of the response filed November 29, 2007, that the claims have been amended to recite the term “*not capable of activating autoreactive cells causing an autoimmune disease*” instead of the previously recited term “*not related to an autoimmune disease*” to better define the genus of peptides to which the claims are directed; yet the instant application does not expressly define the genus of peptides “not related to an autoimmune disease” as including peptides *not capable of activating autoreactive cells causing an autoimmune disease*, and it would not immediately understood to have such meaning from a reading of the instant application, as originally filed. Notably, in accordance with 37 CFR 1.78, the claim or claims must conform to the invention as set forth in the remainder of the specification and the terms and phrases used in the claims must find clear support or antecedent basis in the description so that the meaning of the terms in the claims may be ascertainable by reference to the description.

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Applicant has contended support for this new phrase is found in the specification, as originally filed, at page 11, lines 19-20, which includes a statement of incorporation by reference to WO 01/91698; see, e.g., page 23, line 4-9 of the amendment filed November 29, 2007.

However, contrary to Applicant's contention, the incorporation by reference statement in the instant application does not appear to provide support for the added material because it does not *particularly* identify the added material, and it would not be immediately evident that reference to this international application was made in the instant application with the intention of providing written support for the language of the claims, which otherwise appears to have no basis in the specification, as filed.

According to M.P.E.P. 608.01(p):

Mere reference to another application, patent, or publication is not an incorporation of anything therein into the application containing such reference for the purpose of the disclosure required by 35 U.S.C. 112, first paragraph. *In re de Seversky*, 474 F.2d 671, 177 USPQ 144 (CCPA 1973).

With regard to incorporation by reference, the Federal Circuit in deciding *Advanced Display Systems Inc. v. Kent State University*, 54 USPQ2d 1673 (CA FC), has further opined:

Incorporation by reference provides a method for integrating material from various documents into a host document--a patent or printed publication in an anticipation determination--by citing such material in a manner that makes clear that the material is effectively part of the host document as if it were explicitly contained therein. *See General Elec. Co. v. Brenner*, 407 F.2d 1258, 1261-62, 159 USPQ 335, 337 (D.C. Cir. 1968); *In re Lund*, 376 F.2d 982, 989, 153 USPQ 625, 631 (CCPA 1967). To incorporate material by reference, the host document must identify with **detailed particularity**¹ what specific material it incorporates and clearly indicate where that material is found in the various documents. *See In re Seversky*, 474 F.2d 671, 674, 177 USPQ 144, 146 (CCPA 1973) (providing that incorporation by reference requires a statement "clearly identifying the subject matter which is incorporated and where it is to be found"); *In re Saunders*, 444 F.2d 599, 602-03, 170 USPQ 213, 216-17 (CCPA 1971) (reasoning that a rejection for anticipation is appropriate only if one reference "expressly incorporates a particular part" of another reference); *National Latex Prods. Co. v. Sun Rubber Co.*, 274 F.2d 224, 230, 123 USPQ 279, 283 (6th Cir. 1959) (requiring a specific reference to material in an earlier application in order have that material considered part of a later application); *cf. Lund*, 376 F.2d at 989, 153 USPQ at 631 (holding that a one sentence reference to an abandoned application is not sufficient to incorporate material from the abandoned application into a new application). Whether and to what extent material has been incorporated by reference into a host document is a question of law.

¹ Emphasis added

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See Quaker City Gear Works, Inc. v. Skil Corp., 747 F.2d 1446, 1453-54, 223 USPQ 1161, 1166 (Fed. Cir. 1984) (reasoning that whether a document is incorporated by reference into a patent presents a question of law when determining enablement). *Id.* at 1679-1680.

[Thus] the standard of one reasonably skilled in the art should be used to determine whether the host document describes the material to be incorporated by reference with sufficient particularity. *Id.* at 1680.

Accordingly, in reading the instant specification, it is submitted one of skill in the art would not reasonably conclude that the genus of peptides *not related to an autoimmune disease* encompasses or is equivalent to the genus of peptides *not capable of activating autoreactive cells causing an autoimmune disease* because the instant specification does not expressly define peptides related to an autoimmune disease, nor does it particularly point to a disclosure in WO 01/91698 that defines the genus of peptides *not related to an autoimmune disease*.

In fact, in comparing the claims, as would be amended, one of skill in the art would reasonable conclude that the claims are now directed to far broader subject matter, because while the peptides previously were not related to an autoimmune disease, the peptides might now include, for example, any other peptide which is related to an autoimmune disease, but is not capable of activating autoreactive cells causing an autoimmune disease.

Accordingly, it is apparent that the claims, as would be amended, encompass a genus of peptides which differ so substantially from the breath of the originally presented claims that an examination of the claims would require different considerations and/or searches, which were not before necessary for the originally presented invention. Moreover, the broader scope of the claims, as would be amended, would require a different field of search (e.g., searching additional and/or different classes/subclasses or electronic resources, and/or employing additional and/or different search queries). For example, a prior art search performed to consider the merits of the elected invention would not be applicable, or sufficient to permit a determination of the novelty and/or obviousness of elements encompassed by the far broader scope of the newly presented claims. Notably, for example, in the previous Office action at page 20, the prior art was determined to teach polynucleotides that encode polypeptides comprising a β 2-microglobulin polypeptide linked through its carboxy terminus to polypeptide stretch that

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allow the anchorage of β 2-microglobulin to the cell membrane and through its amino terminus to at least one antigenic peptide comprising a MHC class I epitope, wherein said antigenic peptide is related to an autoimmune disease which does not read on claims reciting antigenic peptides *not* related to an autoimmune disease. However, the prior art has not been searched or considered to determine what the art teaches about the far broader genus of peptides *not capable of activating autoreactive cells causing an autoimmune disease*. Additionally, it is noted that the broader scope of the claims, as would be amended, is likely to raise different non-prior art issues under 35 U.S.C. §§ 101 and/or 35 U.S.C. 112, first paragraph, which pertain to the corresponding utility requirement and/or enablement and/or written description requirements.

As such, examination of the claims, as would be amended, would be unduly burdensome. Notably, the claims, as would be amended, are drawn to an invention not encompassed by the original claims which would require new and different considerations and searches that were not before necessary. Thus, any need to search and consider the claims, as would be amended, would create an undue and serious burden on the Office.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits.

Accordingly, after entry of the amendment, all remaining claims would be withdrawn from consideration as being directed to non-elected inventions, and therefore the amendment, which presents only claims drawn to such non-elected inventions, is non-responsive and will not be entered. See 37 CFR 1.142(b) and MPEP § 821.03.

2. Since the above-mentioned reply appears to be *bona fide*, applicant is given **ONE (1) MONTH or THIRTY (30) DAYS** from the mailing date of this notice, whichever is longer, within which to supply the omission or correction in order to avoid abandonment. EXTENSIONS OF THIS TIME PERIOD MAY BE GRANTED UNDER 37 CFR 1.136(a).

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3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brad Duffy whose telephone number is (571) 272-9935. The examiner can normally be reached on Monday through Friday 7:00 AM to 4:30PM with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Respectfully,
Brad Duffy
571-272-9935

/Stephen L. Rawlings/
Stephen L. Rawlings, Ph.D.
Primary Examiner, Art Unit 1643

/bd/
Examiner, Art Unit 1643
April 7, 2008